AE Detection and Creation (RP15)
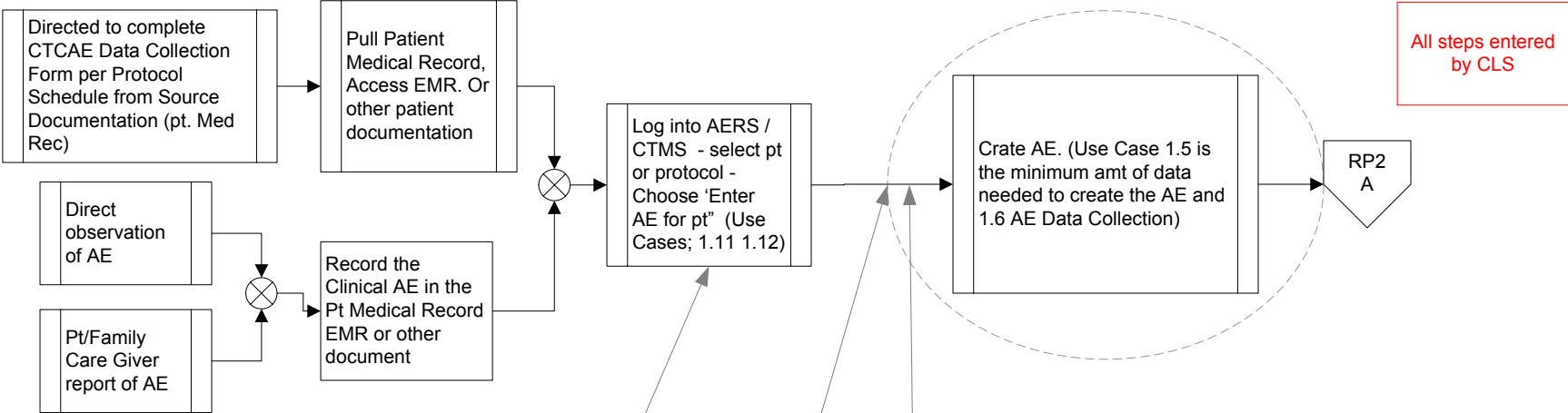
Post accessioning & baseline assessment of study participant; usually post a treatment cycle.

Directed to complete CTCAE Data Collection Form per Protocol Schedule from Source Documentation (pt. Med Rec)

Pull Patient Medical Record, Access EMR. Or other patient documentation

Direct observation of AE

Pt/Family Care Giver report of AE

Record the Clinical AE in the Pt Medical Record EMR or other document

Log into AERS / CTMS - select pt or protocol - Choose 'Enter AE for pt" (Use Cases; 1.11 1.12)

Crate AE. (Use Case 1.5 is the minimum amt of data needed to create the AE and 1.6 AE Data Collection)

RP2 A

All steps entered by CLS

Automated detection/ grading of Lab data is part of Module 11 to be expanded

Preconditions: Protocol and Study Participant created and linked; (Use Cases 1.1, 1.2, 1.3, 1.4)

Preconditions: Add Protocol Data Use Case 1.4: Identify entities expecting an AE report

Preconditions: Institution, Sponsor and Protocol Specific Notification Triggers are defined (Use cases 1.9, 1.10, 1.11)

Nurse